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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,096	09/18/2003	Brian R. MacDonald	PRD-2110-USANP	1638
27777	7590	10/08/2008		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER BUNNER, BRIDGET E	
			ART UNIT	PAPER NUMBER
			1647	
			MAIL DATE	DELIVERY MODE
			10/08/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/667,096

**Applicant(s)**

MACDONALD ET AL.

**Examiner**

Bridget E. Bunner

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-12 and 15-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12 and 15-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 and 01 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 October 2007 has been entered.

Claims 2-12 and 15-34 are under consideration in the instant application.

### ***Withdrawn Objections and/or Rejections***

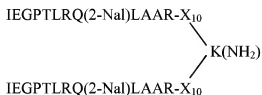
1. The rejection of claims 2-12 and 15-34 under 35 U.S.C. 103(a) as being unpatentable over Fibbe et al. (U.S. Patent 6,013,067) in view of Dower et al. (U.S. Patent 5,869,451) is withdrawn in view of Applicant's persuasive arguments (26 October 2007).

### ***35 U.S.C. 132***

2. The amendment filed 22 May 2006 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. Applicant has introduced new matter at page 7 in the specification. Specifically, the amended description at page 7, between lines 9-10 indicates that a preferred TPO mimetic compound is IEGPTLRQ(2-Nal)LAARX<sub>10</sub> where X<sub>10</sub> is a sarcosine or  $\beta$ -alanine residue or pegylated form of this compound. However, page 7, lines 8-9

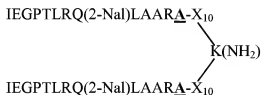
in the original specification of 9/18/03 only recite a preferred TPO mimetic of IEGPTLRQ(2-Nal)LAARA (emphasis added by the Examiner). The original specification does not teach a TPO mimetic monomer missing an alanine at the end of the sequence. The original specification also does not teach a monomer with an X<sub>10</sub> group attached, where X<sub>10</sub> represents a sarcosine or β-alanine residue or pegylated form of the compound.

Furthermore, Applicant has introduced new matter at page 7, between lines 20-21 in the specification. The amended description indicates another preferred TPO mimetic compound with the following formula:



wherein X<sub>10</sub> is a sarcosine or β-alanine residue or a pegylated form of the compound.

However, page 7, lines 13-18 in the original specification of 9/18/03 only recite a preferred TPO mimetic of



wherein X<sub>10</sub> is a sarcosine or β-alanine residue or a pegylated form of the compound (emphasis added by the Examiner). The original specification does not teach a TPO dimer or oligomer missing an alanine between the arginine and X<sub>10</sub> at the end of the sequence.

Applicant is required to cancel the new matter in the reply to this Office Action.

*Claim Rejections - 35 USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The basis for this rejection is set forth at pages 3-4 of the previous Office Action (08 May 2007).

Claim 34 is directed a method of providing hematopoietic stem cells to a subject wherein said subject is treated with radiation therapy.

Applicant's arguments (26 October 2007), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

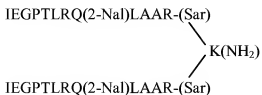
At page 7 of the Response, Applicant asserts that as of the filing data of the application, one skilled in the art would understand that the claimed invention could be employed to treat a subject undergoing radiation therapy. Applicant submits an article (Baynes et al. Clin Chem 46(8 Pt 2): I239-51, 2000) to demonstrate the knowledge in the art.

Applicant's argument has been fully considered but is not found to be persuasive. While Applicant's submission of Baynes et al. demonstrates the knowledge in the art of hematopoietic stem cell transplantation at the time the invention was made, MPEP § 706.03(o) clearly states

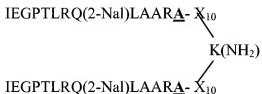
that “subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). As discussed in the previous Office Action, the specification as originally filed does not provide adequate written description for a method of providing hematopoietic stem cells to a subject wherein said subject is treated with radiation therapy. It is not expressly asserted, nor does it flow naturally from the specification. The specification only discloses that “the present invention can also reduce the proportion of subjects who are unable to harvest enough cells to proceed with treatment for their primary illness, e.g., chemotherapy and other bone marrow ablative treatments” (page 8, lines 6-10).

4. Claims 2-12 and 15-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide adequate written description for a TPO mimetic compound having the following sequence: IEGPTLRQ(2-Nal)LAARX<sub>10</sub>, wherein (2-Nal) is  $\beta$ -(2-naphthyl)alanine and X<sub>10</sub> is Sar. The specification as originally filed also does not provide adequate written description for a TPO mimetic having the following formula:



These compounds are not expressly asserted, nor do they flow naturally from the specification. The originally filed specification of 18 September 2003 only discloses that “a particularly preferred TPO mimetic peptide is IEGPTLRQ(2-Nal)LAARA” (page 7, lines 8-9; emphasis added by the Examiner). The originally filed specification also discloses that the mimetic compound is dimerized or oligomerized and an example includes (emphasis added by the Examiner):



wherein  $X_{10}$  is a sarcosine or  $\beta$ -alanine residue or a pegylated form of the compound. Thus, the original specification does not disclose a TPO mimetic *monomer* with an  $X_{10}$  group (Sarcosine) attached (as recited in the claim 2). The specification also does not teach a monomer or dimer without an alanine after an arginine at the end of the sequence.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB  
Art Unit 1647  
29 September 2008

/Bridget E Bunner/  
Primary Examiner, Art Unit 1647